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10/782,287	02/19/2004	Jei-Fu Shaw	70002-104001	4293
69713 7590 1228/2009 OCCHIUTI ROHLICEK & TSAO, LLP			EXAMINER	
10 FAWCETT	STREET		KIM, TAEYOON	
CAMBRIDGE, MA 02138			ART UNIT	PAPER NUMBER
			1651	
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# Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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## Application No. Applicant(s) 10/782 287 SHAW ET AL. Office Action Summary Examiner Art Unit TAEYOON KIM 1651 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 06 November 2009. 2a) This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 14-16.18-20.31-36.45.47.48 and 53-56 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) Claim(s) \_\_\_\_\_ is/are allowed. 6) Claim(s) 14-16,18-20,31-36,45,47,48 and 53-56 is/are rejected. 7) Claim(s) \_\_\_\_\_ is/are objected to. 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some \* c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). \* See the attached detailed Office action for a list of the certified copies not received. Attachment(s) 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413)

Paper No(s)/Mail Date

Notice of Draftsherson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)

Paper No(s)/Mail Date.

6) Other:

5) Notice of Informal Patent Application

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#### DETAILED ACTION

### Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/6/2009 has been entered.

Applicant's amendment and response filed on 11/6/2009 has been received and entered into the case.

Claims 1-13, 17, 21-30, 37-44, 46 and 49-52 have been canceled, claims 53-56 are newly added, and claims 14-16, 18-20, 31-36, 45, 47, 48 and 53-56 have been considered on the merits. All arguments have been fully considered.

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 14-16, 18-20, 31-36, 45, 47, 48 and 53-56 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for those starch hydrolyzing enzyme that hydrolyzes starch to oligosaccharide stable at the temperature coagulating proteins (e.g. a thermostable  $\alpha$ -amylase), does not reasonably provide enablement for those not stable at the

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temperature coagulating proteins. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant claims disclose the use of any starch hydrolyzing enzyme capable of hydrolyzing starch to oligosaccharide, and  $\alpha$ -amylase for such an enzyme. Furthermore, the claims require the enzyme being able to hydrolyze starch at the temperature under which proteins coagulate.

The specification as well as the dependent claims discloses the temperature is 90°C (p.5, lines 29-30; claims 31-36 and 56).

The specification also discloses the use of thermostable  $\alpha$ -amylase for the process (Example 1).

Since it is well known in the art that typical  $\alpha$ -amylase would be deactivated at the temperature disclosed in the instant invention according to Violet et al. (1989; see entire document), the claimed invention which requires the temperature high enough to deactivate/denature non-thermostable  $\alpha$ -amylase or any other non-thermostable starch hydrolyzing enzyme.

Thus, the specification does not provide enablement commensurate with the entire scope of the instant claims.

### Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 14-16, 18-20, 31-36 and 45-50 are rejected under 35 U.S.C. 103(a) as being

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unpatentable over Shaw et al. (1992; Biosci. Biotech. Biochem.) in view of Seidman et al. (of record) in further view of Jones et al. (1927, J. Biol. Chem.), Nutrition Facts on glutinous rice (downloaded from

http://www.nutrientfacts.com/searchfood.exe?keyword=Rice+White+Glutinous+Raw&var=5 on 2009) and Skory et al. (of record).

Shaw et al. teach a method of converting milled rice to high-maltose syrup from milled rice (rice flour) in water forming slurry, followed by liquefaction with  $\alpha$ -amylase, and heating to the temperature to the point of  $\alpha$ -amylase denaturation where all the proteins in the rice flour being essentially heat-coagulated, and removed by centrifugation, and the resulting supernatant was further treated with  $\beta$ -amylase and debranching enzymes to produce the high-maltose syrup (p.1071, under Results and Discussion; Fig. 1).

Although Shaw et al. disclose that autoclaving step up to the temperature of 128°C would carry out liquefaction by thermostable a-amylase and at the same time protein coagulation is performed, which allows easier removal of proteins, Shaw et al. do not particularly teach the temperature used for coagulating protein being 90°C.

However, it is well known in the art that the coagulating temperatures for two globulins present in rice are 74 and 90°C (p.416).

Therefore, it would have been obvious to a person of ordinary skill in the art to use higher temperature (i.e. 90°C) to obtain both of globulins present in rice coagulated in the method of Shaw et al.

The person of ordinary skill in the art would have had a reasonable expectation of success in using the temperature of  $90^{\circ}$ C for the  $\alpha$ -amylase liquefaction step of Shaw et al. carrying out

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heat-coagulation of rice proteins at the same time.

Shaw et al. do not teach the use of a hydrolyzing enzyme that hydrolyzes starch or oligosaccharide to glucose.

Seidman et al. teach a process of liquefying starch derived from rice, tapioca, sorghum, potatoes, etc. (see column 5, lines 6-10) to a soluble hydrolysate using thermostable  $\alpha$ -amylase at a temperature about 170°F-195°F, which is 76.7°C-90.5°C (see column 2, lines 46-60), and then a saccharification enzyme such as glucoamylase in the second step (see column 2, lines 8-12).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try glucoamylase which is used in the second step of Seidman's method to replace β-amylase and debranching enzymes of Shaw et al. to form glucose-rich syrup in the method of Shaw et al.

The skilled artisan would have been motivated to make such a modification because glucose-rich syrup has commonly used for various different industrial purposes including production of fermented products, and also for food industry, and a person of ordinary skill in the art would recognize the method of Shaw et al. can be modified to generate glucose-rich syrup from rice by simply using glucoamylases taught by Seidman et al.

Shaw et al. in view of Seidman et al. do not teach the use of glucose-rich syrup as is for growing a microorganism to produce a fermentation product.

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the glucose-rich syrup of Shaw et al. in view of Sediman et al. for fermentation process.

This is because it is well known in the art that glucose derived from rice is a source for

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fermenting rice wine with yeast or any other ethanologenic microorganisms (e.g. filamentous fungi), and a person of ordinary skill in the art would recognize that the glucose-rich syrup of Shaw et al. in view of Seidman et al. does not require any additional nutrients since rice contains vitamins (particularly, vitamin B such as riboflavin, niacin, folate, thiamin) and phosphorus according to the Nutrition Facts of glutinous white rice (see the table). Furthermore, even though the process removes proteins from rice, which can be source of nitrogen (i.e. amino acids), these vitamin B complex can be also nitrogen sources for microorganisms. Thus, the glucose-rich syrup produced by the method of Shaw et al. in view of Seidman et al. can be used for fermentation (growth of microorganisms) directly without further addition of other nutrients.

Shaw et al. in view of Seidman et al. do not teach the step for producing ethanol by fermentation with Aspergillus oryzae for 3 or 5 days (claims 45-50).

Skory et al. teach a fermentation process of simple sugars (glucose) using Aspergillus oryzae to produce ethanol (fermentation product) (see Table 1), and Skory et al. also show various duration of fermentation including 3-5 days and the yield of ethanol (see Fig.1).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to try to use Aspergillus oryzae to ferment the glucose-rich syrup of Shaw et al. in view of Seidman et al. to produce fermentation product because it is well known in the art that Aspergillus oryzae is one of commonly used fungi in fermentation art.

The Supreme Court recently states in KSR v. Teleflex (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of elements was "obvious to try." Id., at 289 (internal quotation marks omitted). When there is a design need or market

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pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103." See also M.P.E.P. §2141.

With regard to the limitation directed to the glucose concentration being 105 mg/ml or 114 mg/ml, and the limitation directed to the yield of ethanol being 10.5% or 13.5%, Shaw et al. in view of Seidman et al. in further view of Skory et al. do not particularly teach the limitations.

The limitations are directed to the results obtainable from the method claimed in the current application. The limitations do not require any process step to be carried out other than disclosed in the current claims. Thus, the limitation does not limit the method of the current invention. However, since the method steps of Shaw et al. in view of Seidman et al. in further view of Skory et al. is substantially similar, if not identical, the results obtainable from the methods of Shaw et al. in view of Seidman et al. in further view of Skory et al. is expected to be substantially the same as the claimed invention.

Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill at the time the invention was made.

#### Conclusion

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <a href="http://pair-direct.uspto.gov">http://pair-direct.uspto.gov</a>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/ Primary Examiner, Art Unit 1651